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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,388	07/02/2003	Jaeho Kim	279.582US1	3198

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/612,388	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> Carl H. Layno	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-40 is/are allowed.
- 6) ☒ Claim(s) 1,9-12,14,15,20,21,23-26,28,32-34,41 and 43-45 is/are rejected.
- 7) ☒ Claim(s) 2-8,13,16-19,22,27,29-31 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because the drawings are informal. See attached PTO-948 for the Draftsperson's comments. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 9-12, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartley et al (US 6,076,015).

In regard to claim 1, the Hartley et al (US 6,076,015) patent describes an implantable cardiac rhythm management device (CRM) (Fig.1) comprising applicant's claimed features of sensors 120,125,135 for measuring heart related signals, an impedance measurement/sensing circuit 175, and processor 155. The sensing circuits sense invoked transthoracic impedance signals (col.7, lines 47-50). To overcome this rejection, the Examiner recommends replacing the word "processor" with the words "means for processing" thereby invoking 35 U.S.C 112 6<sup>th</sup> paragraph to give the trailing descriptive language patentable weight.

In regard to claim 9, the CRM of Hartley et al is attached to an endocardial lead **110** with two cardiac sensing electrodes **120,125** (Fig.1), and includes an exciter **150**, a signal processor **155**, sampling circuitry **400** (Fig.10), and a housing **130** (Fig.1) having a housing electrode **135**.

In regard to claim 10, applicant's attention is directed to the therapy circuit 170 and controller 165 of Fig.1.

In regard to claim 11, bandpass filter 420 (Fig.4) would inherently perform the function of measuring time intervals from past occurrences since it uses the time differences between the same sensed signals (i.e. interval information) to obtain a "filtered" signal. Calculated impedance values are stored in the processor's memory registers (col.15, line 48-50).

In regard to claim 12, applicant's attention is directed to tidal volume calculations boxes **805** (Figs.8 and 9; col.15, lines 52-67).

In regard to claims 14 and 15, applicant's attention is directed to header **140** and electrode **145** (Fig.1).

4. Claims 9-11, 20, and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Poore (US 2003/003291-A1).

In regard to claims 9 and 32, the Poore (US 2003/003291-A1) patent publication describes an implantable stimulation device (Figs.3 and 4) reading upon applicant's claimed device structure. Specifically, the device is attached to three endocardial stimulation leads **230,220,224** and includes excitation circuit **316** (Fig.4), a signal processing circuit **260**, sampling circuit **312** (p.6, paragraph [0055]), and a housing case electrode **211**. The processing circuit **260**

identifies fiducial marker information such as R-waves or P-waves (Fig. 5 - p.7, paragraph [0060]).

In regard to claim 10, the device comprises pacing therapy circuits **272,270**. The processing circuit **260** performs the function of the “controller” since it sets output pacing rates.

In regard to claim 11, the device includes memory **294** (Fig.4). See Fig.5, blocks **406** and **410** for fiducial marker capabilities (p.7, paragraph [0060]).

In regard to claim 20, switch bank **274** (Fig.4) performs the function of applicant’s “selector”.

5. Claims 21, 23-26, 28, 41, and 43-45 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Baura et al (US 6,561,986).

In regard to claim 21 and 41, the Baura et al (US 6,561,986) patent describes a method and apparatus for detecting fiducial points in an ECG signal to calculate a patient’s transthoracic impedance and cardiac output. Applicant’s attention is drawn to the flow chart of Fig.2, which shows among other steps, the steps of “identifying fiducial points” and sensing/calculating impedance waveforms. In operation, an impedance waveform is obtained by first applying current pulses **1304** (Fig.13) to electrodes placed around the subject’s thoracic cavity (col.22, lines 32-43). The measured resultant voltages are used to help identify fiducial points (**Q, R, B, C, X, and O** – shown in Fig.4, col.22, lines 43-53). Though not in the same order as applicant’s steps, to have re-arranged the order of impedance calculation would have been an obvious, if not inherent, alternative since Baura et al perform the same basic functions as applicant’s claimed

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steps (i.e. identifying fiducial markers based upon heart related signals and calculating a patient's transthoracic impedance).

In regard to claims 23 and 43, fiducial marker locations Q, R, and B (Fig.1) are identified. These appear to correspond to the QRS complex (col.4, lines 60-67).

In regard to claims 24 and 44, marker "R" corresponds to the R-wave (Fig.1).

In regard to claims 25 and 45, marker "X" appears to correspond to the T-wave (Fig.1).

In regard to claim 26, applicant's attention is directed to Fig.3, which shows the use of "Median filters" **323**. The use of filters implies that the device is detecting the periodicity of the fiducial ECG data points (i.e. time intervals between them). The device has a mass storage memory data device **1215** for storing sensed signals (col.21, lines 32-35).

In regard to claim 28, the placement of electrodes across a patient's thoracic cavity would inherently define a vector (col.22, lines 32-43).

#### ***Allowable Subject Matter***

6. Claims 2-8, 13, 16-19, 22, 27, 29-31, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 35-40 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 35 recites a method of treating lung ventilation disorders utilizing a unique combination of steps including those of “detecting fiducial markers”, “calculating impedance”, “determining respiratory activity”, and “providing therapy for stimulating breathing activity”, not found in the prior art. As a result, claims 35 and its depending claims are deemed to be allowable.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Yerich et al (US 5,562,711) patent is cited for its pertinent implantable device structure (Fig.2) including impedance measurement circuits, leads with electrodes, pacing circuits, sensing circuits, and processor circuits. Unlike applicant's device, no mention is made of using “fiducial markers”.

The Larson et al (US 6,868,346) patent describes a device similar to that of Hartley et al ('015) (cited above) but having a less effective filing date; hence, Hartley et al was cited as the basis for a 102(b) rejection versus this reference. This reference is cited for its pertinent structures (Fig.3).

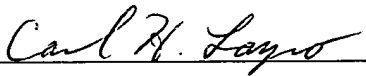
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO  
PRIMARY EXAMINER

CHL  
3/6/2006